

**AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 - EXPEDITED PROCEDURE**

Serial Number: 09/702068

Filing Date: October 30, 2000

Title: Enzymatic Treatment of Whey Proteins for the Production of Antihypertensive Peptides and the Resulting Products

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Dkt: 267.011US1**REMARKS**

Claims 1-3, 5-6, 8-13, 15-32, and 34-36 are amended, and claims 7, 14, and 33 are canceled. Claims 1-3, 5-6, 8-13, 15-32, and 34-39 are now pending in this application. The amendments to the claims are supported by the application as filed, and no new matter has been added.

**I. The Interview Summary**

Applicant would like to thank Examiner Meller for the courtesy extended during the telephonic interviews on November 19 and December 05, 2003. Applicant's attorneys Robert Harris and Peter Malen participated in the November 19 interview, and Applicant's attorney Peter Malen participated in the December 05 interview.

The pending claims and cited art were discussed during the interviews. Examiner Meller indicated that amending the independent claims to recite the molecular weight profile of the hydrolysate would place the claims in condition for allowance. The claims are so amended herein.

Examiner Meller also reviewed U.S. Patent No. 6,630,320 and requested that Applicant file a Terminal Disclaimer over 6,630,320. To expedite prosecution, enclosed herewith is a Terminal Disclaimer over U.S. Patent No. 6,630,320. Applicant has also included herewith a Supplemental Information Disclosure Statement containing U.S. Patent No. 6,630,320. U.S. Patent No. 6,630,320 issued from application Serial No. 09/567,283, an application brought to the Examiner's attention as a related co-pending application in the Amendment and Response filed August 11, 2003.

The above account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication so that Applicant can amend or supplement the interview summary.

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Dkt: 267.011US1**II. Rejoinder of Claim 6 under M.P.E.P. § 821.04**

Claim 6 has been withdrawn from consideration by the Examiner. If product claim 5 or 32 is found to be allowable, rejoinder of claim 6, which recites the administration of the product of claim 5 or 32, is hereby requested.

**III. The 35 U.S.C. § 102 Rejections of the Claims**

The Examiner rejected claims 1, 2, 5, 7-9, 16-27, and 32-39 under 35 U.S.C. § 102(b), alleging that those claims are anticipated by JP 04282400 (hereinafter '400). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent claims 1 and 34 recite processes for preparing dried ACE-inhibiting compositions that include a hydrolysate having a mixture of peptides with a recited molecular weight profile. Claims 5 and 32 recite ACE-inhibiting compositions prepared according to claims 1 or 34 that include a hydrolysate having a mixture of peptides with a recited molecular weight profile. Claims 2, 8-9, 16-24, 26-27, and 35-39 depend either directly or indirectly from claims 1 or 34. Claim 25 depends from independent claims 12 or 13. Claims 7, 14, and 33 are cancelled.

A rejection of anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9<sup>th</sup> Cir. 1981). Applicant respectfully submits that the claims are not anticipated by the cited document.

'400 reports a process for producing a purified peptide described as being an inhibitor of ACE. "The molecular weight of ACE inhibitor peptide ... is less than about 1000." (see the first paragraph of page 2)

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'400 does not teach or suggest a dried whey protein hydrolysate having the recited molecular weight profile nor a process for preparing such a hydrolysate. Accordingly, because '400 lacks the disclosure of each element of the claims under consideration, withdraw of the rejection of the claims under 35 U.S.C. § 102 is appropriate and is respectfully requested.

**IV. The 35 U.S.C. § 103 Rejections of the Claims**

The Examiner rejected claims 1-3, 5, and 7-39 under 35 U.S.C. § 103(a), alleging that those claims are unpatentable over JP 4282398 (hereinafter '398) or '400 taken with JP 04082898 (hereinafter '898) and further taken with Jue et al. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent claims 1, 12, 13, and 34 recite processes for preparing dried ACE-inhibiting compositions that include a hydrolysate having a mixture of peptides with a recited molecular weight profile. Claims 5 and 32 recite ACE-inhibiting compositions prepared according to claims 1, 12, 13, or 34 that include a hydrolysate having a mixture of peptides with a recited molecular weight profile. Claims 2, 3, 8-11, 15-31, and 35-39 depend either directly or indirectly from claims 1, 12, 13, 33 or 34. Claims 7, 14, and 33 are cancelled.

A rejection of obviousness under 35 U.S.C. § 103 requires that the Examiner establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner has the burden to establish three basic elements. First, the Examiner must establish that there is some suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention. Second, the Examiner must establish that there is a reasonable expectation of success. Finally, the Examiner must establish that the prior art documents teach or suggests all the claim limitations. M.P.E.P. § 2143. Applicant respectfully submits that the claims are not *prima facie* obvious in view of the cited documents.

'400 is described hereinabove.

Similarly to '400, '398 also reports the production of a purified peptide. The purified peptide of '398 contains the specific amino acid sequence Phe-Asp-Lys (see the first sentence of the Abstract).

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'898 reports a process for producing the tripeptide Leu-Lys-Pro from whey protein by hydrolysis with an aspartic proteinase, followed by extensive purification (see the Example on page 3). This peptide is described as being an inhibitor of ACE.

Ju et al. relates to food products and describes a process for manipulating gelation properties of whey proteins via limited proteolysis.

Applicant respectfully submits that the claims are not *prima facie* obvious in view of the cited documents for at least the following reasons. (1) None of the cited documents teach or suggest a dried whey protein hydrolysate having the recited molecular weight profile nor a process for preparing such a hydrolysate. Therefore, any combination of the cited documents fails to teach or suggests all the claim limitations. (2) Additionally, '400, '398, and '898 report processes involving extensive purification to produce their respective purified peptides. Therefore, the art worker would not have a reasonable expectation that a mixture of peptides having the recited molecular weight profile would be useful as an ACE-inhibiting hydrolysate, and would thus not be motivated to prepare a whey protein hydrolysate having the recited molecular weight profile. (3) Finally, Ju et al. relates to manipulating gelation properties of whey proteins. It is respectfully submitted that the art worker would not have been motivated to combine Ju et al. with the cited Japanese documents. Thus, Applicant respectfully submits that the claims are not *prima facie* obvious in view of the cited documents, and withdraw of the rejections of the claims under 35 U.S.C. § 103 is appropriate and is respectfully requested.

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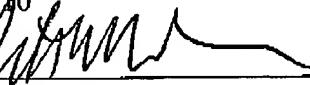
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Dkt. 267.011US1**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is requested. The Examiner is invited to telephone Applicant's attorney (612-371-2110) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,  
MARTIN E. DAVIS ET AL.  
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 371-2110

Date 12-18-03By   
Peter L. Malen  
Reg. No. 44,894

The undersigned hereby certifies that this correspondence is transmitted by facsimile (FAX NO. 703-872-9306) to: Attn.: Examiner Michael Moller, GAIU 1654, Mail Stop AP, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18th day of December, 2003.

Name

Dawn M. Boole

Signature

Dawn M. Boole